JAN 1 6 2002

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

K014124

December 14, 2001

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED COEfficient PTV Catheter; Class II

Predicate Devices: NuMED Z-MED PTV Catheter

Device Description: The COEfficient PTV Catheter is a coaxial over-the-wire catheter with a balloon near the distal tip. One lumen permits guidewire insertion to facilitate advancement of the catheter into the pulmonary valve while the other lumen is for balloon inflation and deflation. The balloon of the COEfficient model is made of a non-compliant polyethylene. The balloons are designed to inflate to a specific diameter at a given pressure. The change in diameter is minimal over the range of inflation pressures. The catheter body ends proximally in a bifurcated 'Y' connector with a guidewire port and a balloon extension. The balloon extension is marked with the product lot number and the balloon size. The outer body and inner body tubing is made of pebax. The area under the balloon is enhanced with either one or two radiopaque platinum image bands depending on the model. If marked with one image band, it is centered under the midpoint of the balloon. If it is marked with two image bands, they are located under the shoulders of the balloon. This catheter is of the same design and construction as the NuMED PTV catheters for which the 510(K) has been approved. The differences are lower profile, smaller shaft, and higher rated burst pressure.

Biocompatibility Testing: The materials used in the NuMED COEfficient Catheter are the same as those used in our other PTA Catheters (510(k) #K931009) and PTV Catheters (510(k) #K991977) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

Intended Use: This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Comparison Information:

MODEL:	NUMED COEFFICIENT PTV	NUMED Z-MED PTV
Indications:	This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve. ▪ A patient with isolated pulmonary stenosis ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.	This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve. ▪ A patient with isolated pulmonary stenosis ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.
Introducer:	4 Fr – 7 Fr	6 Fr – 14 Fr
Shaft Size:	3.5 Fr	5 Fr – 11 Fr
Guidewire Size:	0.018"	0.018", 0.021", 0.025", and 0.035"
Usable Length:	75 cm	85 cm, 100 cm, 110 cm, and 120cm
Balloon Diameter:	4 mm – 12 mm	2 mm – 20 mm, 22 mm – 26 mm, 28 mm, 30 mm, 33 mm, 35 mm, 35 mm, 40 mm.
Balloon Length:	2 cm – 4 cm	1 cm – 15 cm
Materials:	Shaft: Pebax Balloon: PES2 Image Band: Platinum	Shaft: Pebax Balloon: PES2 Image Band: Platinum
Construction:	Coaxial construction with distally mounted non-compliant balloon.	Coaxial construction with distally mounted non-compliant balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2002

Ms. Nichelle LaFlesh
Regulatory Affairs Manager
NuMED, Inc.
2880 Main St.
Hopkinton, NY 12965

Re: K014124
COEfficient PTV Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II
Product Code: MAD
Dated: December 14, 2001
Received: December 17, 2001

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K014124

Device Name: **NuMED COEfficient PTV Catheter**

Indications For Use:

This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(K) Number K014104